(12) UK Patent Application (19) GB (11) 2 222 954 (13) A

(43) Date of A publication 28.03.1990

(21) Application No 8919604.2

(22) Date of filing 30.08.1989

(30) Priority data
(31) 3830005 (32) 31.08.1988 (33) DE
3830481 08.09.1988

(51) INT CL⁴
A61L 27/00

(52) UK CL (Edition J)
A5R RAG

(56) Documents cited
None

(58) Field of search
UK CL (Edition J) A5R RAG RAM RAP RAR
INT CL⁴ A61F, A61L

(71) Applicant
Ethicon Inc

(Incorporated in the USA - New Jersey)

U.S. Route #202, Somerville, New Jersey,
United States of America

(72) Inventor
Lothar Schilder

(74) Agent and/or Address for Service
Carpmaels and Ransford
43 Bloomsbury Square, London, WC1A 2RA,
United Kingdom

(54) Implant

(57) The invention relates to an implant of resorbable material, which is characterized in that it comprises a woven or knitted tubular or flat structure, whose filaments or fibres either completely or portionwise comprise at least two different resorbable materials with different melting points, which, after heating to a temperature above the melting point of the resorbable material with the lower melting point and below the melting point of the other resorbable material with the higher melting point, are shaped or pressed to a composite of the desired configuration. Tubular structures may additionally comprise a woven or knitted tube of one resorbable material (2a) which is completely or portionwise covered or coated with an inner or outer, film-like layer (10) of the other resorbable material.

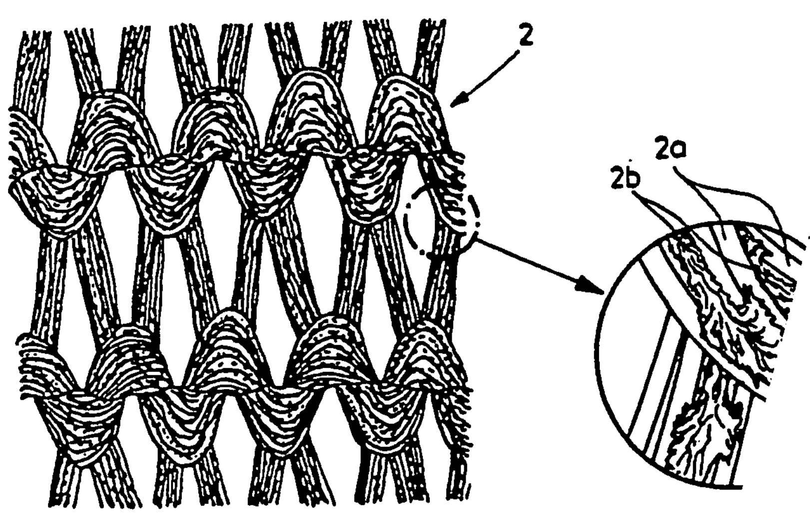


FIG.1

At least one drawing originally filed was informal and the print reproduced here is taken from a latr

2222954

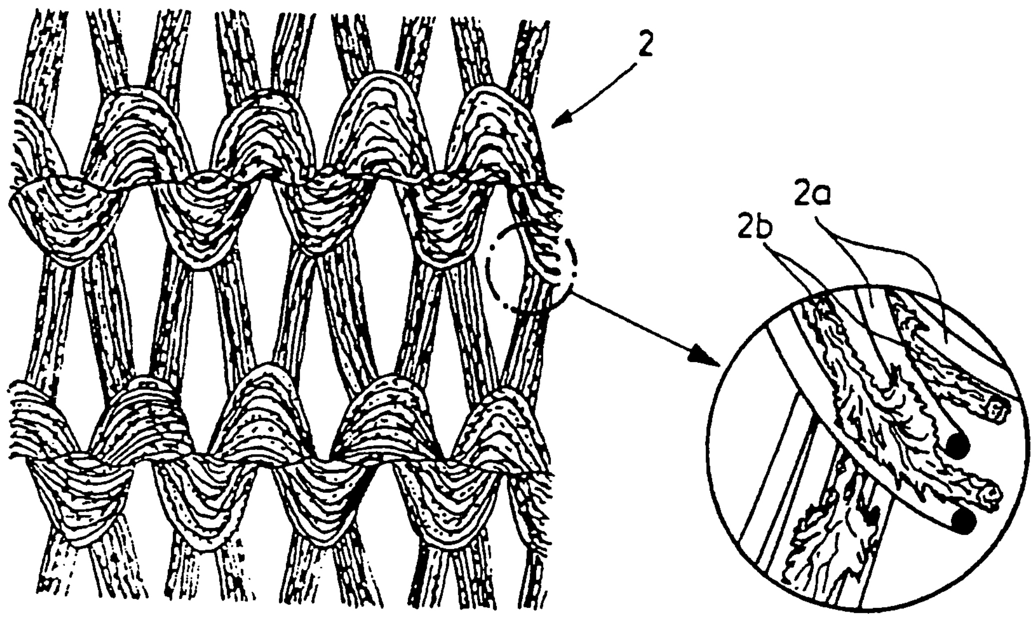


FIG.1

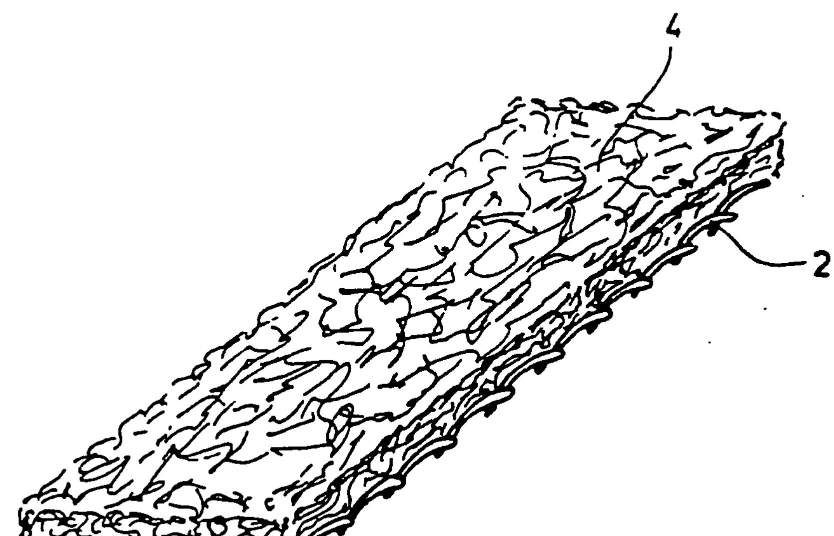


FIG. 5

Fig 1a

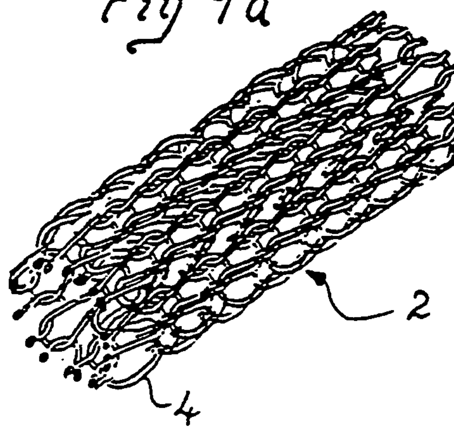


Fig 2

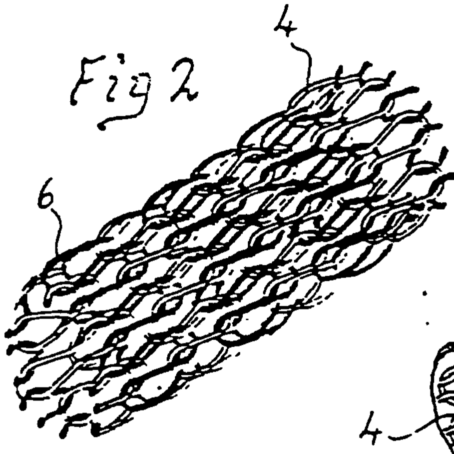


Fig 3

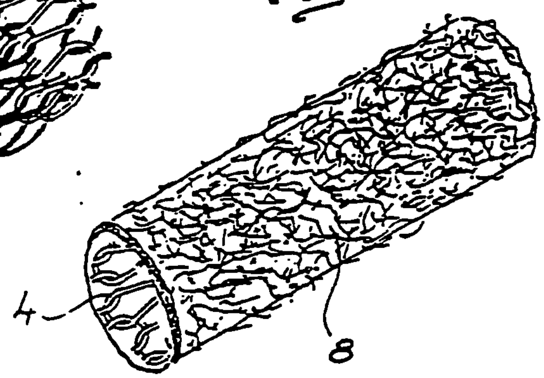
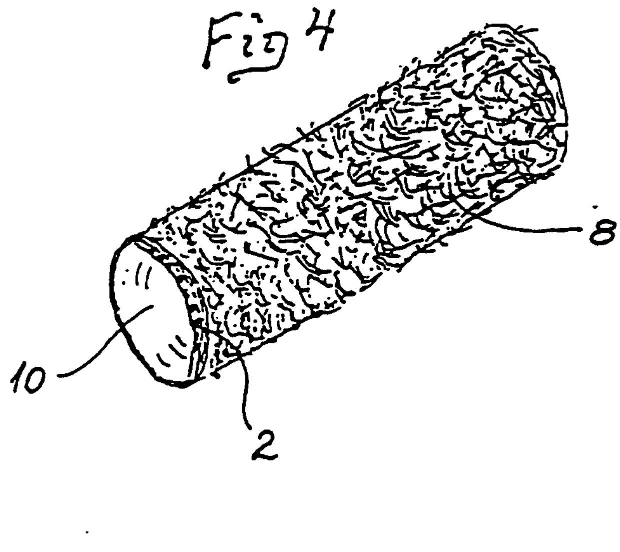


Fig 4



2222954

3/3

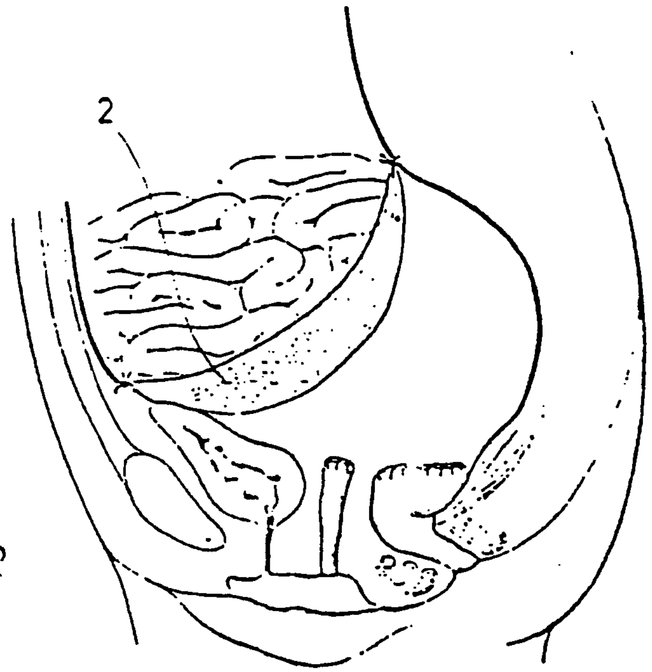


FIG. 6

FIG. 7

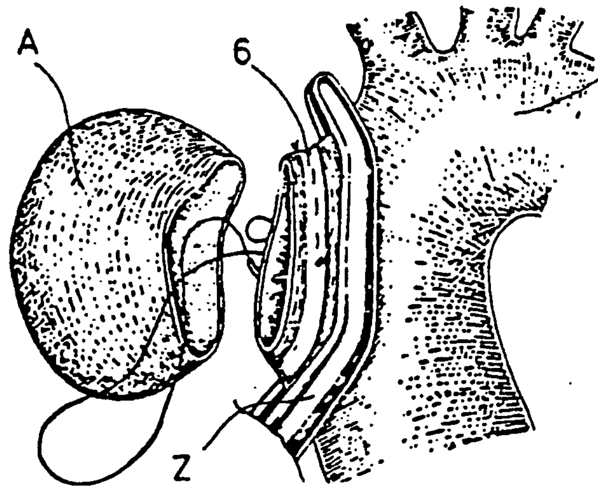
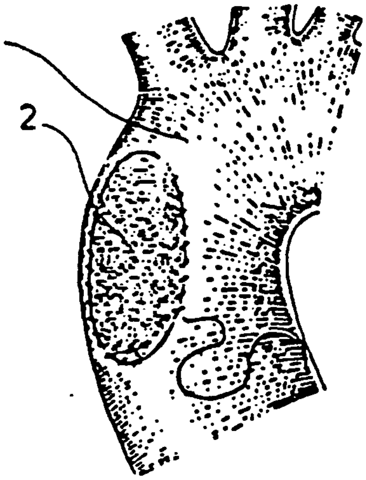


FIG. 8



2222954

3/3

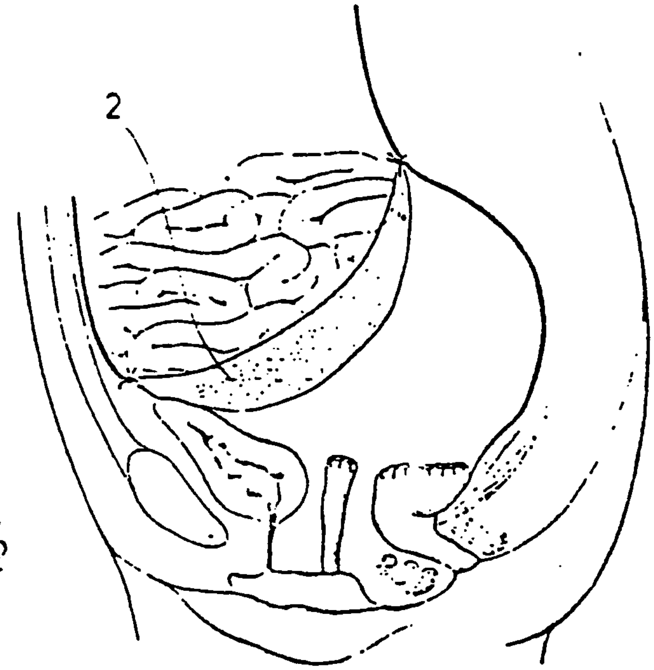


FIG. 6

FIG. 7

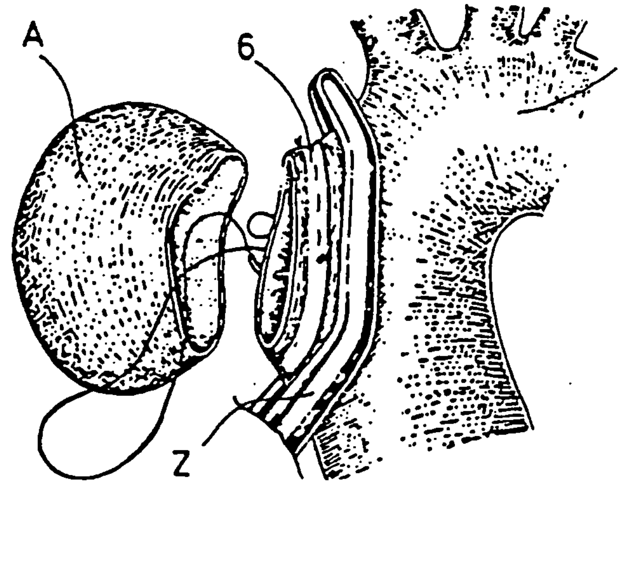
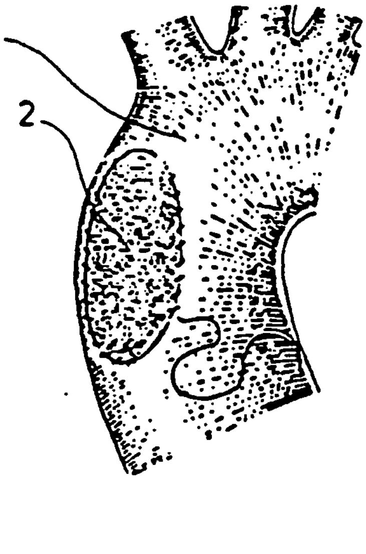


FIG. 8



SURGICAL IMPLANT AND PROCESS FOR THE PRODUCTION THEREOF

Field of Invention

The invention relates to flat and surgical implants made from resorbable material, as well as to a process for its production.

Background of the Invention

Flat implants are e.g. known from US patent 3,739,773. They comprise flat or velour-like products, which are used e.g. in several layers or with a sponge-like structure for the treatment of burns or other skin injuries, as well as for other purposes. As a result of their porosity they are able to absorb tissue fluid and are gradually permeated by tissue and which, following complete resorption of the implant, takes over its supporting and holding function.

However, these textile-like fabrics can only be used to a limited extent as a result of their limited thickness and rag-like characteristics.

U.S. Patent No. 4,796,603 discloses cushion or pad-like implants, whose outer sleeve comprises a knitted tube of filaments or fibres of a resorbable plastic and are filled with threads, filaments, flocks or shreds of another resorbable plastic and these plastics can have different resorbability characteristics. These tubular pads or

cushions have a compressability of at least 50% and are particularly suitable for the treatment of hernias.

In addition, tubular implants from a unitary resorbable polyglycolic acid ester, namely a polyglactin are known, which e.g. according to E. Kruger in Dtsch. Z. Mund- und Kiefergesichts Chir. 9, pp 194-195, 1985 are filled with hydroxyl apatite and are used for building up or reinforcing the maxillary crest. Moreover, F. Schier et al in Z. Kinderchir., 42, pp 224 to 227 have already tested an oesophagus replacement of resorbable Vicryl tubes in veterinary experiments.

Recently foam-like implants of a unitary, resorbable polyglycolic acid ester have become known, e.g. from US patent 4,186,448. Such sponge-like or foam-like implants suffer from the disadvantage that they still contain impurities as a result of the constituents necessary for foaming and said impurities are compatible with the tissue. In addition, such foam-like implants have a uniform resorption duration.

A fundamental disadvantage of surgical implants obtained from monofilaments of resorbable material by weaving or knitting is that said material loses its formed structure, at least in the edge regions, after cutting or separating, because the monofilaments are relatively bulky and unravel at the cutting points unless complicated knitting machines are used to produce mesh-strong fabrics, whose mechanical loadability leaves much to be desired.

The problem of the present invention is to propose a surgical implant, which can be cut and sewn in, which has a considerable mechanical strength, but is still adequately porous in order to allow tissue to grow into it

and preferably has a different resorbability within the entire implant. In addition, tubular implants are proposed which are not only suitable for placing granular material, such as hydroxyl apatite, in certain body cavities, but are also suitable for alloplastic hollow organ replacement, e.g. as a replacement for the oesophagus, trachea, blood vessel and ureter.

To solve this problem a surgical implant according to the main claim is proposed, particularly preferred embodiments being given in the subclaims.

Summary of Invention

It has surprisingly been found that a knitted or woven structure of at least two different resorbable materials with different melting points, heated to a temperature above the melting point of the resorbable material with the lower melting point and below the melting point of the other resorbable material with the highest melting point, gives a composite implant which, as a result of the substantially surface bonding of the individual filaments, can be cut, gives a smooth cut edge, has the desired strength and can be varied as a function of the production method with respect to the mesh size or pore size.

The knitted or woven structure may be tubular or flat. Woven strips can, for example, be advantageously used in capsular ligament surgery of the knee joint and in numerous other cases in osteosynthesis, the higher mechanical strength and the longer in vivo strength of the flat composite being advantageous. In a preferred embodiment a tubular structure has reinforced ring regions with a width of 1 to 5 mm, said ring regions being made from a less flexible material.

In another preferred embodiment, fine-meshed structures are coated with a felt layer of a resorbable material. In this connection, either the woven or knitted tube or flat material is covered prior to heating with a fibrous mixture of resorbable fibres with a length of e.g. 5 to 12 mm and is then shaped, or the already obtained composite is covered in felt-like manner with the fibrous mixture of resorbable material with different melting points and is then heated again to e.g. 100 to 120°C. The advantage of these composite structures with a felt layer is based on the fact that as a result of the felt upper layer, the structures obtained are blood-tight and can therefore be used in various different ways, e.g. as vessels and in connection with vessels for supporting the suture or directly as a vessel patch.

In another preferred embodiment the inside of the tubular implant is made from a sheet of an also resorbable material, which is joined in unitary manner to the hose to form a composite implant.

To produce this composite implant, the tubes are produced, preferably on a circular knitting machine, as a seamless, tubular knitted article. The tubes can obviously also be produced in the form of a woven article. The thread guidance can be controlled in such a way that the fibres or filaments can be randomly processed from the plastics with different melting points. It is also possible to place the lower melting material either to the outside or to the inside.

The tube made from the fibres or filaments is drawn onto a shaping bar, e.g. a round bar or pipe and is heated under an inert gas, such as nitrogen, to a temperature of 100 to 120°C.

In a variant of the process, a tubular film of a resorbable material can be applied to a shaping bar and the preferably circular knitted tube of resorbable material can be drawn over the shaping bar covered with the film. Either the tubular film or the tube or a part of its filaments or fibres comprise the lower melting, resorbable plastic and subsequently, once again under inert gas, the composite is produced at temperatures of 100 to 120°C.

According to another variant the tube drawn onto the shaping bar can also be provided with felt-like filaments, which are pressed on and subsequently heated under inert gas.

Resorbable polymers with a good physiological compatibility are known per se. Typical representatives are poly-p-dioxanones, commercially available under the abbreviation PDS and which, from the chemical standpoint, are aliphatic polyesters of poly-p-dioxanone, can be extruded to monofilaments and melt at 85 to 95°C. They are described in "Ethicon OP Forum", No. 108, 1981 and in J. Pediatr. Ophthalmol. 13, pp 360-364, 1976.

In another group of resorbable materials appear polyglactins, which are a copolymer of glycolide and lactides and which can also be extruded to fibres, being commercially available under the registered trademark Vicryl and which are e.g. described in detail in "Ethicon OP Forum", No. 96, 1978 and in J. Pediatr. Ophthalmol. 13, p 360, 1976. This group also includes lactide-glycolide block copolymers according to DE-OS 28 49 785. As a function of the degree of polymerization, these polyglactins have a melting point of approximately 180 to 200°C.

As a function of the nature of the resorbable material and the degree of polymerization, the resorbability differs. In the case of the higher melting polyglactins, it is e.g. in a range of 60 to 80 days, whereas for the lower melting poly-p-dioxanones it is approximately 200 days. By corresponding mixing of the monofilaments or fibres forming the felt-like covering material on the implant, it is possible to control the resorption time of the complete implant, i.e. the speed with which the implant can be decomposed.

Particular reference is given to a mixture of poly-p-dioxanone fibres and polyglactin fibres in a ratio of 5:1 to 1:15 and particularly 1:3.

Due to the fact that the fibrous mixture is heated within the different melting points of the resorbable materials and then shaped, there is a strengthening of the fibres of the higher melting, resorbable material by melting-on bonding of the filaments or fibres of the resorbable material with the lower melting point, so that a porous structure is obtained.

Drawings

The invention is described in greater detail hereinafter relative to the drawings, wherein show:

Fig. 1 A detail of a knitted composite.
Fig. 1a A portion of the tubular implant.
Fig. 2 A tubular implant of a composite with reinforcing rings.
Fig. 3 A portion of a tubular implant with a felt-like covering.

Fig. 4 A portion of an implant as in Fig. 3 with an inner covering of a tubular film.

Fig. 5 A part sectional representation of a composite gauze covered with a felt layer.

Fig. 6 A view of the use of an inventive gauze.

Fig. 7 A view of the use of an inventive strip on removing an aneurysm.

Fig. 8 A view similar to Fig. 7 concerning the use of an inventive flat implant on closing the internal diameter of an aneurysm.

Detailed Description

Example 1

In accordance with Fig. 1, a knitted article is produced on a circular knitting machine with a diameter 4 mm mesh size, namely from mixed filaments 4 of on average 10 filaments of a polyglactin melting at 180°C, with a thread thickness of 60 dtex and 1 filament of a poly-p-dioxanone melting at approximately 90°C and with a thread thickness of 20 dtex. This tube 2 comprising polyglactin filaments 2a and poly-p-dioxanone filaments 2b shown in Fig. 1 was heated on a round bar under nitrogen at 120°C, so as to give a composite tube.

This tube shown in Fig. 1a comprised mixed filaments 4, in which the proportion of lower melting filaments was relatively low.

If less elastic or slightly flexible tubular implants are required, the proportion of lower melting poly-p-dioxanone threads is increased, so that a greater strengthening of the gauze structure occurs.

Example 2

In order to produce an alloplastic hollow organ replacement, a tube according to Fig. 2 was produced on a circular knitting machine and in order to obtain strengthened ring regions filaments or fibres of a mixture of poly-p-dioxanone and polyglactin in a ratio of 5:1 to 1:1 were used. As a function of the intended use, these stiffer ring portions 6 can be 1 to 5 mm wide and make it possible to bend the tubular implant whilst maintaining the internal diameter unchanged.

Example 3

A tube according to Example 1 was produced. This tube shown in Fig. 3 was covered with cut small monofilaments 8 of poly-(lactide-coglycolide) and poly-p-dioxanone in a mixing ratio of 3:1 with an average thread length of 6 to 11 mm, followed by heating under pressure at 100°C. A felt-like tubular implant was obtained, which was blood-tight and could be successfully used in vessel surgery.

Example 4

A 0.1 mm thick tubular film of poly-p-dioxanone was produced and drawn over a bar. A tube produced according to Example 1 was then drawn over said film and the complete structure was inserted in a channel adapted to the bar and which was lined with felt filaments according to Example 3, followed by coating with further felt filaments and then pressing under nitrogen at a temperature of approximately 110°C.

All the tubes produced according to the invention can be readily cut, sewn in, flexible whilst keeping open the internal diameter, are transversely and longitudinally elastic, porous and tight to water, blood and air and, in the embodiment according to Example 4, have a smooth inner surface. They can be produced with simple means and in a relatively simple manner.

Example 5

Using a straight knitting machine a knitted article in accordance with Fig. 1 was produced having a diameter 4 mm mesh size, namely from mixed filaments of on average 10 filaments of polyglactin melting at 180°C and having a thread thickness of 60 dtex and 1 filament of a poly-p-dioxanone melting at approximately 90°C and with a thread thickness of 20 dtex. This fabric 2 of polyglactin filaments 2a and poly-p-dioxanone filaments 2b shown in Fig. 1 was pressed hot under nitrogen at 120°C and a composite fabric was obtained.

In a width of 30 x 20 cm and as shown in Fig. 6, this fabric 2 was used for sealing off the minor pelvis from the abdominal cavity after fixing the gauze on the promontory, the lateral pelvic wall and the ventral abdominal wall.

In the same way flat structures of this type can be used in connection with spleen, kidney and transplant ruptures, as well as for liver ruptures for supplying the organs.

If less elastic or flexible flat implants are required, the proportion of lower melting poly-p-dioxanone threads is increased, which leads to a further strengthening of the gauze structure.

Example 6

A mesh fabric as in Example 1 was prepared. This mesh fabric 2 shown in Fig. 5 was covered with cut small monofilaments of poly-(lactide-coglycolide) and poly-p-dioxanone in a mixing ratio of 3:1 with an average thread length of 6 to 11 mm and heated under pressure to 100°C. A felt-like, flat implant was obtained, which was blood-tight and which could be used as a reinforcing strip in connection with sutures, in the case of cardiac wall injuries and for vessel surgery.

Example 7

For removing a bag-shaped aneurysm of the ascending aorta, the procedure shown in Figs. 7 and 8 was adopted.

Following the clamping off of the vessel with forceps Z, the bag-shaped aneurysm A of the aorta was removed and the internal diameter was closed by a continuous mattress suture by means of a strip 6 of an implant according to the invention. The strip was constituted by a flat knitted fabric with a thread ratio of polyglactin to poly-p-dioxanone of 8:1 and which had a tensile strength of 200 N.

In a parallel case, the internal diameter was closed by an over-cut, flat woven fabric 2, as shown in Fig. 8 and which consisted of a flat composite fabric of polyglactin and poly-p-dioxanone in a ratio of 10:1, the former having a thread thickness of 60 dtex and the latter a thread thickness of 66 dtex, the mesh size being 0.2 mm.

Example 8

In a further case, for suture reinforcement in surgery, so-called pledgets were produced from a mixed fabric, in which the threads of the higher melting polyglactin were present in a ratio of 5:1 to the threads of the lower melting poly-p-dioxanone and all the threads had a titre of 40 detex. This strip material with a mesh size of 0.3 mm was heat sealed under nitrogen at 120°C and allowed very satisfactory processing.

CLAIMS

1. Tubular implant of resorbable material, characterized in that it comprises a woven or knitted tube (2), whose filaments or fibres

a) either completely or portionwise comprise at least two different resorbable materials (2a, 2b) with different melting points or

b) one resorbable material (2a) and are coated or covered completely or portionwise with an inner or outer film-like layer (10) of the other resorbable material,

which, after heating to a temperature above the melting point of the resorbable material (2b) with the lower melting point and below the melting point of the other resorbable material (2a) with the higher melting point are shaped or strengthened to a tubular composite.

2. Implant according to claim 1, characterized in that the outside of the tube is covered or coated with a felt-like layer (8) of resorbable material.

3. Implant according to claim 2, characterized in that the tube is covered in felt-like manner with a mixture of 1 to 20 mm long filaments or fibres of at least two different resorbable materials with different melting points and is heated and shaped at a temperature of 100 to 120°C.

4. Implant according to claim 1, characterized in that the resorbable materials have a different resorption time.

5. Implant according to claim 1, characterized in that the fibres or filaments comprise a lower melting poly-p-dioxanone and a higher melting polyglactin in a mixing ratio of 5:1 to 1:15.

6. Implant according to claim 5, characterized in that the mixing ratio of the fibres or filaments of poly-p-dioxanone and polyglactin is approximately 1:3.

7. Implant according to claim 1, characterized in that the pores or mesh sizes in the woven or knitted, tubular composite is 0.1 to 4 mm.

8. Implant according to claim 1, characterized in that the filaments or fibres have a diameter of 10 to 200 dtex.

9. Implant according to claim 1, characterized in that the tube has reinforced ring regions (6) with a width of 1 to 5 mm, whose fibres and filaments comprise a mixture of lower melting poly-p-dioxanone and a higher melting polyglactin in a mixing ratio of 5:1 to 1:1, whilst the gaps comprise a mixture in the ratio 1:1 to 0.5:15.

10. Process for producing a tube according to claim 1, characterized in that the tube produced from fibres or filaments of at least two different resorbable materials with different melting points is drawn onto a shaping bar and heated under inert gas to a temperature of 100 to 120°C.

11. Process for producing a tube according to claim 1, characterized in that a tubular film (10) of a resorbable material is applied to a shaping bar and a woven or knitted tube of resorbable material is drawn over the shaping bar covered with the film, in which either the tubular film (10) or the tube (2) or a part of the filaments or fibres thereof are formed from a lower melting, resorbable plastic and are heated under inert gas to a temperature of 100 to 120°C.

12. Process according to claims 10 and 11, characterized in that onto the tube located on the shaping bar are pressed felt filaments, followed by heating under inert gas.

13. Flat implant of resorbable material, characterized in that it comprises woven or knitted gauzes, strips or ribbons, whose filaments or fibres comprise at least two different resorbable materials with different melting points and which, after melting to a temperature above the melting point of the resorbable material with the lower melting point and below the melting point of the other resorbable material with the higher melting point, are shaped or pressed to a flat composite.

14. Implant according to claim 13, characterized in that the resorbable materials have a different resorption time.

15. Implant according to claim 1, characterized in that the fibres or filaments comprise a lower melting poly-p-dioxanone and a higher melting polyglactin in a mixing ratio of 5:1 to 1:15.

16. Implant according to claim 15, characterized in that the mixing ratio of the fibres or filaments of poly-p-dioxanone and polyglactin is approximately 1:3.

17. Implant according to claim 1, characterized in that the pores or mesh sizes in the woven or knitted flat composite are 0.1 to 4 mm.

18. Implant according to claim 1, characterized in that the filaments or fibres have a diameter of 10 to 200 dtex.

19. Implant according to claim 1, characterized in that the woven or knitted material or the flat composite is covered in felt-like manner with a mixture of 1 to 20 mm long filaments or fibres of at least two different resorbable materials in knitted or woven form and having different melting points and is heated and shaped at a temperature of 100 to 120°C.

20. An implant, substantially as hereinbefore described with reference to the accompanying drawings.

21. A process for producing an implant, substantially as hereinbefore described with refernce to the accompanying drawings.

Published 1990 at The Patent Office. State House. 66 71 High Holborn, London WC1R 4TP. Further copies may be obtained from The Patent Office. Sales Branch. St Mary Cray. Orpington. Kent BR5 3RD. Printed by Multiplex techniques ltd. St Mary Cray. Kent. Con. 1/87